EUROPEAN
COMMISSION

Brussels, 10.8.2022
C(2022) 5917 final

COMMISSION IMPLEMENTING DECISION

of 10.8.2022

relating to the designation of "Clarithromycin, clofazimine, rifabutin" as an orphan medicinal product under Regulation (EC) No 141/2000 of the European Parliament and of the Council

(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1], and in particular the first sentence of Article 5(8) thereof,

Having regard to the application submitted by Regintel Limited on 18 May 2022 under Article 5(1) of Regulation (EC) No 141/2000,

Having regard to the favourable opinion of the European Medicines Agency, drawn up on 14 July 2022 by the Committee for Orphan Medicinal Products and received by the Commission on 22 July 2022,

Whereas:

(1) The application submitted by Regintel Limited concerning the medicinal product “Clarithromycin, clofazimine, rifabutin” was validated on 14 June 2022 under Article 5(4) of Regulation (EC) No 141/2000.

(2) "Clarithromycin, clofazimine, rifabutin" meets the designation criteria referred to in Article 3(1) of Regulation (EC) No 141/2000.

(3) The application should therefore be accepted,

HAS ADOPTED THIS DECISION:

Article 1

The medicinal product “Clarithromycin, clofazimine, rifabutin” is designated as an orphan medicinal product for the indication: Treatment of nontuberculous mycobacterial lung disease. It shall be entered in the Community Register of Orphan Medicinal Products under number EU/3/22/2687.

[1] OJ L 18, 22.1.2000, p.1.

Article 2

The European Medicines Agency shall make available to all interested parties the opinion of the Committee on Orphan Medicinal Products referred to in this Decision.

Article 3

This Decision is addressed to Regintel Limited, Templetown, Carlingford A91 X097, Co. Louth, Ireland.

Done at Brussels, 10.8.2022

For the Commission

Sandra GALLINA
Director-General

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION